International Journal of Science and Research (IJSR) ISSN: 2319-7064 ResearchGate Impact Factor (2018): 0.28 | SJIF (2018): 7.426

A Prospective Comparative Study between 10ml & 15ml of Normal Saline for Epidural Volume Expansion, with 10mg of 0.5% Intrathecal Hyperbaric Bupivacaine for Elective Surgeries Up to Umbilical Level in Adult Patients

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Abstract: Introduction: The Epidural Volume Expansion (EVE) technique is a modification of CSE, Study is aimed to compare the two Normal saline volumes (NS) (10ml and 15ml) for EVE on spinal anaesthesia with 10 mg of 0.5% hyperbaric bupivacaine for elective surgeries up to umbilical level, with respect to sensory, motor blockade and haemodynamics. <u>Methodology</u>: 90 patients of both sexes, aged between 18-60 years, with ASA grade I & 2, are taken and divided into 3 groups, A,B,C(n=30) Group A received 2ml of 0.5% Bupivacaine intrathecally without EVE. Group B received 2ml of 0.5% hyperbaric Bupivacaine and EVE of 10ml NS, and Group C received2ml of 0.5% hyperbaric Bupivacaine and EVE with 15ml NS.The data obtained was analysed using Cramer's V test, Independent T-test and Anova. <u>Results</u>: Maximum level of a sensory blockade is seen in Group C. Time for two-segment regression maximum in Group B, Duration of Anaesthesia is highest in Group B, Duration of Motor Blockade is highest in Group B. Bradycardia, hypotension more in Group C. <u>Conclusion</u>: EVE of 10 ml of saline with intrathecal 0.5% Bupivacaine is better compared to EVE of 15 ml of saline with regard to sensory and motor block and hemodynamic stability

Keywords: Epidural, Combined spinal-epidural, Epidural volume expansion

1. Introduction

Epidural extends from foramen space magnum tosacralhiatus and surrounds the dura matter anteriorly, laterally and posteriorly¹. Epidural Anaesthesia is achieved by placing a catheter in the epidural space. Combined spinalepidural (CSE) is the technique in which both spinal and epidural anaesthesia are administered simultaneously². Epidural Volume Expansion (EVE), it is a modification of CSE, where the level of sensory analgesia after spinal anaesthesia is increased by injecting normal saline or local anaesthetic through epidural catheter³.EVE can combine the rapidity, density of subarachnoid block with the flexibility of continuous epidural block to titrate a desired sensory level, the intensity of block, duration of anaesthesia and provide post-operative analgesia⁴. The most common mechanism that explains the epidural volume expansion is the thecal compression due to the volume effect.⁵Different volumes of normal saline were tested in the previous studies but there is no consensus regarding the effective volume of normal saline for epidural volume expansion on the sensory and motor block characteristics of spinal anaesthesia. This study is aimed to compare two volumes of normal saline 10ml and 15ml.

2. Materials and Methods

After taking ethical committee approval, 90 patients in the age group between 18 to 59 years of American Society of Anaesthesiologists (ASA) class I and II undergoing elective

surgery upto umbilical level were selected for the study. It is a prospective comparative study conducted at Rangaraya Medical College, Kakinada from 2018 to 2019.

Exclusion Criteria: Patients with body mass index > 30 kg/ m2, patients having any absolute contraindications for spinal anaesthesia like hypovolemia, raised intracranial pressure, bleeding diathesis, local infection and patients with severe comorbid diseases like diabetes, hypertension, cardiovascular diseases, psychiatric and neurologic diseases.

The study population was divided Randomly into 3groups of 30 patients each by using computer-generated randomisation.

Group A: received 10mg (2ml) of 0.5% Hyperbaric Bupivacaine intrathecally without epidural volume expansion. (n=30)

Group B: received 10mg (2ml) of 0.5% Hyperbaric Bupivacaine intrathecally and 10ml of 0.9% Normal Salinefor epidural volume expansion.(n=30)

Group C: received 10mg (2ml) of 0.5% Hyperbaric Bupivacaine intrathecally and 15ml of 0.9% Normal Salinefor epidural volume expansion. (n=30)

Preoperative assessment was done in detail and informed written consent was taken. Patients were kept nil per oral, 8 hrs for solids and 2 hrs for clear fluids before surgery. All the patients received tablet ranitidine 150mg and tablet alprazolam 0.5mg the night before surgery. An intravenous line was obtained with 18G cannula and preloaded with

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International Journal of Science and Research (IJSR) ISSN: 2319-7064 ResearchGate Impact Factor (2018): 0.28 | SJIF (2018): 7.426

Ringer Lactate 10mL/kg half an hour before anaesthesia. Monitoring was done using multiparameter monitor having Pulse oximetry, Electrocardiography (ECG), and Non-InvasiveBlood Pressure (NIBP). Under aseptic precautions, the combined spinal-epidural blockade was performed in laterally flexed position using a double segment technique at either L2-L3 or L3-L4 interspace through a loss of resistance (LOR)to air technique. After placing the epidural catheter, spinal block was performed at either at L3- L4 or L4-L5intervertebral space through a midline approach using 25guage Ouincke spinal needle and after confirming free and clear flow of CSF, 0.5% hyperbaric bupivacaine 10 mg (2ml) was injected at rate of 0.2 ml/second with operative table kept horizontal. The epidural catheter was secured and patients were turned to supine posture immediately. Immediately after turning the patient to the supine position, epidural volume expansion was done with either 10 ml or 15 ml normal saline. The following parameters were observed and recorded, Onset of sensory block at T 10 and motor blockade (Modified Bromage 1), Maximum level of sensory blockade attained and the time taken for the same was noted. Two segments sensory regression time (defined as recovery of sensory blockade by two segments from the highest level of sensory block achieved), total duration of sensory blockade(time of injection till the subject feels sensation at S1) and total duration of analgesia (time for spinal injection and first request for analgesics) were noted. Maximum motor blockade attained and the total duration of motor blockade(attainment of modified Bromage score of 0) were noted.Quality of sensory blockade was tested using the pinprick method with a blunt 27G hypodermic needle. Quality of motor blockade was assessed by a modified Bromage scale. (0 = no paralysis; 1 = unable to raiseextended leg; 2 = unable to flex knee; 3 = unable to flex ankle).Haemodynamic monitoring for heart rate, systolic, diastolic and mean arterial pressure, ECG and SPO2 blood pressure (SBP), was done every minute for first 5minutes, every 5 minutes till the end of surgery. The patient was monitored during the postoperative period for the duration of analgesia and side effects like hypotension and bradycardia and respiratory depression. Hypotension was defined as a reduction of systolic blood pressure (SBP) more than 30% below baseline or fall in SBP less than 90 mm of Hg, and it was treated with IV fluid bolus and if the needed increment of injection Mephentermine 6mg IV. Bradycardia was defined as a heart rate less than 60 beats/minute and was treated with injection Atropine 0.6mg IV.

Statistics

Determination of sample size was done using Anova. Thirty patients were included in each group. The dataobtained were analysed using Cramer's V test, Independent T-test and Anova. Data were entered into Microsoft Excel and all the statistical methods were carried out through the SPSS for Windows (version 23.0). p-value of < 0.05 was considered significant.

3. Results

Table 1: Gender distribution of study participants

| Group | Male | Female | P-value |
|---------|------------|------------|---------|
| Group A | 22(37.28%) | 8(25.80%) | |
| Group B | 18(30.50%) | 12(38.70%) | 1.27 |
| Group C | 19(32.22%) | 11(35.50%) | |
| Total | 59(100%) | 31(100%) | |

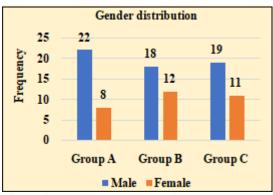


Figure 1: Gender distribution of study participants

 Table 2: Demographic data of study population

| Variable | Group A | | 01040 | F | Р |
|---------------|-------------|------------------|-------------------|-------|-------|
| | (Mean±S.D) | (Mean±S.D) | (Mean±S.D) | value | value |
| Age in years | 35.13±9.23 | 34.62±10.14 | 36.81±11.23 | 0.37 | 0.68 |
| Weight in kgs | 62.91±5.23 | 63.54 ± 5.46 | 63.98±6.12 | 0.27 | 0.76 |
| Height in cms | 163.16±6.23 | 164.21±7.56 | 165.32 ± 7.64 | 0.68 | 0.50 |
| BMI | 22.81±1.56 | 22.48 ± 1.89 | 22.93±2.12 | 2.72 | 0.07 |

Table 3: Distribution of cases based on the type of surgery

| Type of surgery | Frequency | Percentage |
|-------------------|-----------|------------|
| Umbilical hernia | 5 | 5.5% |
| Inguinal hernia | 44 | 49% |
| hydrocele | 23 | 25.5% |
| Incisional hernia | 18 | 20% |
| Total | 90 | 100% |

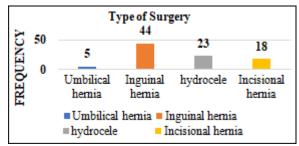


Figure 2: Type of Surgery

 Table 4: Comparison of Sensory block characteristics between groups

| Variable | Group A | Group B | Group C | F | Р |
|--|--------------------|--------------------|--------------------|--------|-------|
| | (Mean±S.D) | (Mean±S.D) | (Mean±S.D) | value | value |
| Onset of sensory block | 2.45±0.81 | 2.31±0.21 | 2.26±0.13 | 1.21 | 0.30 |
| The time required to achieve the maximum level of sensory block (in min) | 5.12±0.78 | 4.63±0.61 | 4.82±0.74 | 3.59 | 0.03 |
| Time for two segment regression (in min) | 81.64±15.24 | 118.26 ± 20.89 | 97.31±18.62 | 29.92 | 0.001 |
| Time for complete sensory regression (in min) | 124.02 ± 25.63 | 208.13±33.21 | 209.35 ± 34.56 | 72.89 | 0.001 |
| Total duration of anaesthesia (in min) | 127.23 ± 26.32 | 216.31±32.15 | 210.45 ± 21.89 | 101.30 | 0.001 |
| Time for first Rescue analgesia (in min) | 128.12 ± 25.38 | 217.48±31.56 | 211.23±18.21 | 113.58 | 0.001 |

Volume 9 Issue 1, January 2020

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International Journal of Science and Research (IJSR) ISSN: 2319-7064 ResearchGate Impact Factor (2018): 0.28 | SJIF (2018): 7.426

 Table 5: Comparison of the maximum level of sensory

 blockade among groups

| blockade among groups | | | | | | |
|-----------------------|-------|-------|-------|-------|--|--|
| Maximum level of | Group | Group | Group | P- | | |
| Sensory blockade | А | В | С | value | | |
| T2 | 0 | 4 | 14 | | | |
| T4 | 0 | 24 | 16 | | | |
| T6 | 2 | 2 | 0 | | | |
| T8 | 10 | 0 | 0 | 0.00 | | |
| T10 | 13 | 0 | 0 | | | |
| T12 | 5 | 0 | 0 | | | |

 Table 6: Comparison of Motor block characteristics

 between groups

| between groups | | | | | | | |
|--|------------------|-----------------------|------------------|------------|-------------|--|--|
| Variable | Group A | Group B (Mean±S.D) | Group C | F value | P- value | | |
| | (Inicali_5.D) | (mean_S.D) | (Inicall_S.D) | value | value | | |
| Time of | | | | | | | |
| Onset of | 2.71±0.91 | 2.41±0.82 | 2.23±0.69 | 2.67 | 0.07 | | |
| Motor block | | | | | | | |
| The time required to achieve the maximum level of the Motor block (in min) | 2.88±0.41 | 2.98±0.32 | 3.12±0.11 | 4.62 | 0.01 | | |
| Total duration of motor block(in min) | 110.26± 16.32 | 187.64± 28.12 | 161.25± 14.78 | 109.17 | 0.001 | | |

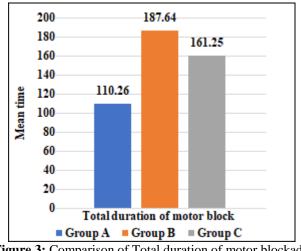


Figure 3: Comparison of Total duration of motor blockade between groups

4. Discussion

Central Neuraxial blockade has seen several modifications in recent times; an epidural is a gold standard for analgesia. Combining both the spinal and epidural anaesthesia has got both the advantages this is called combined spinalepidural(CSE). Epidural Volume Expansion(EVE) is the modification of epidural, in EVE normal saline is used these days commonly. The advantage in EVE lies in its ability to combine the rapidity, density, and reliability of the subarachnoid block with the flexibility of continuous epidural block to titrate a desired sensory level, vary the intensity of the block, control the duration of anaesthesia and deliver postoperative analgesia. The disadvantages are due to the high sensory level after epidural expansion and due to severe hypotension. Various mechanisms have been described to explain the rapid extension of the sensory block that occurs with EVE include a 'volume effect', 'drug effect' and augmentation of a pre-existing area of subclinical analgesia. The most commonly extended explanation for EVE is the thecal compression due to the "volume effect" on consequent epidural injection of fluid6. This thecal compression causes cephalad shift of local anaesthetic within the cerebrospinal fluid, raising the level of sensory block. Imaging studies documented thecal compression following EVE and severalstudies demonstrate an increase in the post-spinal sensory block following epidural injection of normal saline.5

Sensory Block Characteristics

In our study, the time of onset of sensory blockade was similar (2.26 minutes- 2.45 minutes) among the threegroups. This result of our study correlates with other studies (Doganci et al., Lew et al. and Salman et al.) which showed no difference in time of onset of sensory blockade when different volumes of EVE were used in lower limb surgeries.7,8, In current study there was a statistically significant difference between the groups regarding level of maximum sensory blockade (T2), it was 43.3% of patients in group C and 10% of patients in group B, which is consistent with Okasha et al. study Chiraynth J et al. .9,10Time for two-segment regression was longest in group B (118.26 \pm 20.89 minutes) as compared to group C(97.31 \pm 18.62 minutes) which was longer when compared to group A $(81.64 \pm 15.24 \text{ minutes})$. Faster regression of sensory blockade in group C, when compared to group B, could be due to greater spread of drug, exposing the drug to a larger area for vascular absorption and thus a shorter duration of action.11 This finding is consistent with Okasha et al. study and Salman et al. .9,3 The time for complete sensory regression was longest in group C(209.35 \pm 34.56 minutes) as compared to group B(208.13 \pm 33.21 minutes)which was longer than group A (124.02 \pm 25.16 minutes).Hence, early epidural catheter activation was required in the control group as compared to EVE groups. Time for a request of rescue analgesia was longer ingroup B as compared to group C and group A.First request of rescue analgesia was longer in EVE groups as compared to the group without EVE

Motor Blockade Characteristics

In our study, time of onset of motor blockade and maximum motor blockade were similar among the threegroups which correlate with Doganci et al. study.⁷Result ofour study correlates with Sherin M A et al. study which also showed similar Bromage scores among the groups.13Duration of motor blockade was longest in group B(187.64 \pm 28.12minutes) as compared to group C (161.25 \pm 14.78 minutes) which was still longer as compared to group A (110.26 \pm 16.32 minutes).This result is consistent with Salman et al. and Goy RWL et al. study.³

Haemodynamic Effects

When comparing the intraoperative heart rate and mean arterial pressure between the groups, both the EVE groups(10 ml and 15 ml) showed fall in heart rate and mean arterial pressure below the basal values at various time intervals. This difference was statistically significant after 10 minutes of EVE.Incidence of bradycardia was higher in

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group C as compared to group B.The incidence of bradycardia was still less in group 0 when compared to EVE groups (10ml,15ml). Regarding mean arterial pressure, a fall in MAP was more in group C as compared to group B which was less in group A as compared to EVE groups.

Adverse Effects

When comparing adverse effects among study groups, ten patients had hypotension in group C whereas only 3 patients had hypotension in group B after 10 minutes of EVE. Even in group A, two patients had hypotension after 10 minutes of spinal block. Hence the incidence of hypotension was significantly high in group C when compared to group B.Our study result correlates with Sherin M A et al. study.13 Bradycardia was also seen in the study groups. 11 patients had bradycardia in group C as compared to group B where only 4 patients had bradycardia after 10 minutes of EVE and only one patient in group A had bradycardia after 10 minutes of spinal blockade. Hence the incidence of bradycardia was significantly high in group C when compared to group B.

5. Conclusion

EVE of 10 ml of saline with intrathecal 0.5% Bupivacaine is better compared to EVE of 15 ml of saline with regard to sensory and motor block and hemodynamic stability.

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Volume 9 Issue 1, January 2020 www.ijsr.net

DOI: 10.21275/ART20204421